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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,356	03/31/2004	Mark S. Zeiner	END-5008CIP2	8274

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
YABUT, DIANE D	

ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,356	ZEINER, MARK S.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 21 August 2006.
2. Examiner acknowledges that an IDS has not been filed and the corrections made to the specification, to Figure 1, and to Claims 4,8,10,16, and 24. Examiner reconsiders and withdraws objection to change "to maintain insuflation" to "to maintain insulation" on page 11, paragraph 36.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 1,5,6,7,9,13-15,17 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hart et al.** (U.S. Patent No. **5,385,553**) in view of **Chin** (U.S. Patent No. **6,610031**) and further in view of **Danks et al.** (U.S. Patent No. **5,364,372**), **Antoon, Jr. et al.** (U.S. Patent No. **5,628,732**), and **Hasson et al.** (U.S. Patent No. **5,743,884**).

Claims 1, 9, and 17: Hart discloses a trocar **10** with a cannula **22** having an access ("hollow") channel **24** with a distal end and proximal end and a valve housing **28** attached to the proximal end of the cannula, wherein the proximal end has a wall with an aperture through which instrument **26** is inserted (Figures 1-3). Hart discloses the claimed device except for the seal assembly comprising a first and second substantially

rigid ring and a plurality of axially interwoven layered elastomeric members with circumferential gaps compressed therebetween, the elastomeric members being circumferentially discontinuous, with first and second rings having distally and proximally extending protrusions, respectively.

Chin discloses a valve assembly with compression members **140** ("first substantially rigid ring") and **141** ("second substantially rigid ring") (Figure 1, col. 4, lines 10-12). Also disclosed is a plurality of layered elastomeric members **132** compressed between the first and second rings (Figure 1, col. 3, lines 34-35 and 60-63). Chin teaches that the configuration of the rings and members provide compression and support so that the surface of the elastomeric members are compressed toward the open portion of their adjacent members so that no continuous unoccupied opening or channel is present, thus retaining sealable control (Figures 3-4, col. 6, lines 52-65). It would have been obvious to one of ordinary skill in the art at the time of invention to add a seal assembly with a plurality of layered elastomeric members, as taught by Chin, to the device of Hart et al. in order to maintain sealable control of the valve assembly.

Antoon, Jr. et al. also discloses a seal with a ring with distal prongs **40** ("protrusions) extending from a distal surface (Figure 3). Also, Danks et al. discloses a membrane seal for a cannula that has a ring-shaped base with proximal mounting posts **99** ("protrusions") extending from a proximal surface (Figure 9). It would have been obvious to one of ordinary skill in the art to add protrusions to both sides, as taught by Antoon, Jr. et al. and Danks et al. combined, to the device of Hart and Chin, since it was

known in the art that there can be protrusions on either or both of two connecting elements depending on the desired strength of connection.

Hasson et al. teaches a sealing structure with axially interwoven layered elastomeric members with circumferential gaps compressed therebetween, the elastomeric members being circumferentially discontinuous, which is beneficial in serving as a mechanism to connect the plurality of elastomeric members as an assembly which deform in succession when compressive force is distributed on the elastomeric members, allowing an instrument to be directed through the sealing mechanism (Figure 14 and col. 9, lines 62-67 and col. 10, lines 1-15). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the axially interwoven, layered, circumferentially discontinuous elastomeric members with circumferential gaps, as taught by Hasson et al., to Hart et al., Chin, Danks et al., and Antoon, Jr. et al., in order for the elastomeric members to serve as an assembly that deforms in succession and allows for an instrument to be directed through the sealing mechanism.

Claims 5,13, and 21: Hart discloses a plurality of seal protectors that comprises outer leaves **105** and **107** and inner leaves **125** and **127** (Figures 9-10, col. 6, lines 48-68).

Claim 6,14, and 22: Chin discloses layered elastomeric members having a substantially centrally located aperture **137** in the seal assembly (Figures 3-4).

Claim 7,15, and 23: Chin discloses layered elastomeric members that are "woven" or combined together (Figures 3-4), according to its definition in The American Heritage®

Dictionary of the English Language: Fourth Edition: the past partiple of weave, or "to interweave or combine (elements) into a complex whole."

5. Claims 2-4,8,10-12,16,18-20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hart et al.**, **Chin**, **Antoon, Jr. et al.**, and **Danks et al.** as applied to Claims 1, 9, and 17 above, and further in view of **Honkanen et al.** (U.S. Patent No. **4,655,752**).

Claims 2,10, and 18: Hart et al., Chin, Antoon, Jr. et al, and Danks et al. disclose the claimed device except for the plurality of elastomeric members forming a conical shape. Honkanen et al. discloses a cannula with a conically-shaped seal **55** (Figure 4). Honkanen et al. teaches that the conical shape assists in the formation of a tight seal about the instrument being inserted since fluid pressure will cause the conical seal member to collapse into the instrument and make it adhere more securely thereto (col. 4, lines 53-58). It would have been obvious to one skilled in the art to incorporate a conical shape to the plurality of elastomeric members as taught by Honkanen et al. to the combined device of Hart et al., Chin, Antoon, Jr. et al., and Danks et al., in order to assist in a more secure adhesion to the inserted instrument.

Claims 3,11, and 19: Honkanen et al. teaches the conical shape seal (see explanation for Claims 2,10, and 18 above), which has a proximal flange portion **56** and an inwardly extending conical portion **58** (Figure 2), which would be disposed between and are abutting against the rings in the device of Chin.

Claims 4,12, and 20: Hart et al. teaches a floating outer portion **39** (Figure 12, col. 2, lines 6-18) which is disposed around the seal assembly of Chin.

Claims 8,16, and 24: Honkanen et al. teaches the conical shape seal (see explanation for Claims 2,10, and 18 above), and when combined with the seal assembly of Chin, the plurality of elastomeric layers have a non-planar shape prior to being assembled.

Response to Arguments

6. Applicant's arguments with respect to Claims 1, 9, and 17 have been considered but are moot in view of the new ground(s) of rejection, necessitate by Applicant's amendment.

Applicant argues that Hart et al., Chin, Antoon, Jr. et al., and Danks et al. do not teach or suggest the new limitations added to the amended Claims 1, 9, and 17 of axially interwoven layered elastomeric members with circumferential gaps compressed therebetween, the elastomeric members being circumferentially discontinuous. The examiner disagrees because the motivation for the combination is presented in paragraph 4 above. The coil-shaped sealing mechanism of Hasson et al. reads on these newly added limitations.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER